REMARKS

Applicant and his attorney have considered the Examiner's comments in the Office Action of April 8, 2003, and submit that claims 36-39, 41-43, 46-48 and 50, as presently amended are allowable over the applied references.

Claims 36-39, 41-43, 46-48 and 50 stand objected to and rejected in view of the prior art. Claims 1-35 and 52-65 are withdrawn from consideration as being directed to a non-elected invention. Claims 40-44, 45, 49 and 51 are withdrawn as being drawn to a non-elected species. For the reasons set forth below, applicant submits that the elected species is patentable, and that claims 40-44, 45, 49 and 51 are allowable for this reason.

Applicant notes that in paragraph No. 3 of the Office Action, claims 40-44 are indicated as withdrawn from consideration as being drawn to a non-elected species. However, at paragraph No. 8, claim 41 is acted upon, and at paragraph No. 10, claims 41-43 are acted upon. Clarification is requested. Possibly the Examiner meant to note in paragraph No. 3 that claims 40 and 44 were withdrawn as being directed to a non-elected species, and that the notation 40-44 is a typographical error. This interpretation appears to follow the Examiner's action, and also comports with the substance of claims 40-44. If a response to the rejection of claims 41-43 is appropriate, applicant submits that these claims are allowable as presently recited. Claims 41-43 depend either directly or indirectly from independent claim 36, which as amended is submitted as allowable for the reasons set forth below. These arguments also support the allowance of claims 41-43.

Responding to paragraph 5 of the Office Action, U.S. non-provisional application Serial No. 09/198,798 has been flagged as lost, as indicated in the attached e-mail communication from the USPTO Tech Center. Applicant is following up this situation, and will advise the examiner of the

status of application 09/198,798 as soon as this situation is resolved.

Responding to paragraph 6 of the Office Action, claim 36, the only independent claim under consideration has been amended to recite the relationship between the step of determining an F factor, and determining a hormone disorder-effective amount of a therapeutic agent using the F factor. The basis for the present amendment to claim 36 can be found in the specification at page 14, lines 6-12 and line 17. See also: page 12, line 3 and Fig. 10 of the drawings. Therefore, no new matter has been added in amending claim 36. Applicant submits that, as amended, claim 36, and those claims depending from claim 36, are now in a form that overcomes the Examiner's objection.

Responding to paragraph 8 of the Office Action, applicant submits that independent claim 36 defines patentable subject matter over the Cavazzo reference (U.S. Patent No. 4,362,719). The Cavazzo reference only describes the daily administration of reduced amounts of a specific insulin formulation in a liquid carrier to treat juvenile diabetes mellitus. Specifically this reference does not disclose, teach nor suggest the step of measuring the concentration of insulin, estrogen, testosterone and SHBG in a mammal serum sample, nor the steps of determining an F factor, and using that F factor to determine a hormone disorder-effective amount of the therapeutic agent, as specifically recited in independent claim 36 as presently amended. Similarly, the reference patent discloses no equation for determining an F factor, as clearly set forth in claim 36.

Applicant agrees that although the Cavazzo reference discloses a method of administering insulin to treat diabetes, the method described in the reference in no way teaches or suggests the steps set forth in applicant's claim 1. Therefore, applicant submits that claim 36 is allowable over the Cavazzo reference.

Applicant respectively traverses the rejection of claims 36, 39, 41-43, 46-48 and 50 as being

obvious over Cavazza in view of the Moinet et al. abstract. The deficiencies evident in applying the Cavazza references to independent claim 36 of the present application have been amply pointed out above. The Moinet et al. reference also fails to teach the specific steps recited in claim 36 regarding (1) measuring the concentration of insulin, estrogen, testosterone and SHBG in a mammal serum sample, (2) determining an F factor, and (3) using the F factor to determine a hormone-effective amount of therapeutic agent. The Moinet et al. reference has been applied by the Examiner merely for its disclosure that percutaneous administration of an insulin-containing formulation can be used to treat non-insulinopaenic diabetes. Neither the Moinet et al. or Cavazza references, taken alone or in combination, teach the steps specifically recited in applicant's amended claim 36, for determining an appropriate hormone disorder-effective amount of a therapeutic agent to be administered to restore hormone balance in a mammal.

Applicant takes exception to the Examiner's conclusions in the last paragraph of paragraph 10 (page 5) of the Office Action. None of the applied references discuss, teach, nor suggest the steps of making a determination of a hormone disorder-effective amount of a therapeutic agent by initially measuring the concentration of insulin, estrogen, testosterone and SHBG in a sample of mammal serum, combined with determining an F factor in an equation using the data obtained from the initial measurements. Such steps, as specifically recited in applicant's claim 36 would not be a mere result of judicious selection and routine optimization. Applicant has presented for patenting a specific process for restoring hormone balance in a mammal, including steps that are not found in the prior art. Therefore, applicant submits that claim 36 does not teach a process that would be obvious to one skilled in the art.

Since dependent claims 37-39, 41-43, 46-48 and 50 all depend from claim 36, each of these

claims are submitted as allowable as depending from an allowable claim.

CONCLUSION

In view of the above amendments to independent claim 36, and the remarks distinguishing applicant's claims from the applied prior art, applicant submits that claims 36-39, 41-43, 46-48 and 50 are allowable.

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Respectfully submitted,

Howard B. Rockman

Howard B. Rockman
Registration No. 22,190
Attorney for Applicant

Barnes & Thornburg
P.O. Box 2786
Chicago, Illinois 60690-2786
(312) 214-4812 Telephone
(312) 759-5646 Facsimile
hrockman@intelpro.com E-Mail